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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/782,590

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ROSE

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EXAMINER

LINGAR, S

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/782,590

Applicant(s)

Rose

Examiner

Ungar

Group Art Unit
1642



☒ Responsive to communication(s) filed on Nov 29, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-87 is/are pending in the application.

Of the above, claim(s) 1-68 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 69-83 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

1. The Amendment filed November 29, 2000 (Paper No. 32) in response to the Office Action of May 25, 2000 (Paper No. 27) is acknowledged but has not been entered. The Declarations filed November 29, 2000 (Paper No. 31) in response to the Office Action of May 25, 2000 (Paper No. 27) are acknowledged and have been entered. Previously pending claims 69, 71, 72 and 78 have been amended. Claims 69-83 are currently being examined.

2 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. It is noted that amendment to the claims has not been entered because the submitted amendment is improper. Claim amendments must be made in accordance with 37 CFR 1.121(b) which requires that addition of phrases or words to a claim may only be made by underlining below the word or words to be added. Claim 77 is improperly amended.

4. The following rejections are maintained:

Claim Rejections - 35 USC § 112

5. Claims 69-83 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 10, Section 5(a) pages 5-8, Paper No. 15, Section 5, pages 2-5 and in Paper No. 27, Section 6, pages 3-6.

Applicant argues that (a) the first therapeutic agent of claim 69 is not therapeutic per se, (b) the first therapeutic agent is radiolabeled it is therapeutic per se, (c) Applicant reiterates the argument that the specification is enabling because ADEPT provides sufficient guidance for doses and methods of administration, (d) the treatment of cancer with radio-labeled antibodies and the treatment of thyroid

Art Unit: 1642

cancer with radio-iodide enable the claims, (e) even without *in vivo* working examples, the specification is enabling for the treatment, for example of tumor and Applicant has unpublished *in vitro* data demonstrating that an immobilized enzyme converted soluble precipitable material (akin to the first therapeutic agent) to an insoluble indigo precipitate, (f)(i) Applicant submits sample calculations for a prophetic treatment of thyroid cancer and points to the Mayers Declaration, (ii) the Mayers Declaration argues (1) that it is the whole complex that provides the therapy, since many of the agents termed therapeutic are not capable of providing therapeutic effect, (2) goes on to give a general discussion of enzymatic action on indoxyl compounds and cites *in vitro* experiments. It is noted that the first line of paragraph 2 of page 4 is illegible.(3) The Mayers Declaration argues that in the field of tumor biology, it is known that tumors have very low flow rates and lack macrophages, lymphocytes and monocytes and in view of these known facts, one of skill in the art would expect to successfully treat tumors with the invention as claimed, (g) applicant claims immobilization of a radioisotope and claims a first extracellular precipitate, (h) Applicant admits on the record that the claimed therapeutic agent is not therapeutic until converted by the action of a first enzyme and cites the Rapoport and Mayers Declarations . The Rapoport Declaration argues that (i) an individual experienced in organic and synthetic chemistry can make soluble precipitable materials and that indoxyl chemistry is well known in the art and (2) reiterates the teaching of the specification drawn to production of soluble precipitable materials, (I) the first therapeutic agent will function as claimed in the

Art Unit: 1642

present invention and that the first extra-cellular precipitate will remain in the tumor tissue.

The arguments have been considered but have not been found persuasive because (a') the agent claimed is the first agent and it is claimed as a therapeutic agent. Applicant admits on the record that it is not therapeutic, (b') as drawn to claims 69-82, applicant is arguing limitations not recited in the claims as currently constituted. As drawn to claim 83, for the reasons previously set forth, in the absence of experimental evidence no one of skill in the art would find it more likely than not that the invention of claim 83 would function as claimed, (c') the argument has not been found persuasive for the reasons previously set forth in Paper No. 15, Section 5, page 4 item, further, Applicant admits on the record that the claimed therapeutic agent is not therapeutic per se (d') - (f') Applicant is arguing limitations not recited in the claims as presently constituted. Applicant is not claiming a method of treatment of cancer, applicant is claiming a therapeutic agent which Applicant admits on the record is not therapeutic, (g') Applicant is arguing limitations not recited in the claims as presently constituted, the claims are specifically drawn to a therapeutic agent being a soluble precipitable material. Neither an immobilized radioisotope nor a precipitate is claimed, (h) the Mayers Declaration is not persuasive for the reasons set forth above, further, as drawn to the Rapoport Declaration, Applicant does not address the issue raised drawn to the claimed therapeutic agent. It is clear from the responses received that the claimed therapeutic agent is not therapeutic per se, (i') Applicant is arguing limitations not recited in the claims as presently constituted for the reasons set forth above. The

Art Unit: 1642

claims are not drawn to a precipitate as disclosed above but rather to a therapeutic agent which applicant admits on the record is not therapeutic per se. Applicant's arguments have not been found persuasive and the rejection is maintained.

6. Claims 69-83 remain rejected under 35 USC 112, first paragraph essentially for the reasons disclosed in Paper No. 10, Section 5(b) pages 8-10, Paper No. 15 Section 6, pages 5-6 and Paper No. 27, Section 7, pages 6-7.

Because Applicant did not distinctly and specifically point out the supposed errors in the rejection, the rejection is maintained.

7. Claims 69-83 remain rejected under 35 USC 112, first paragraph essentially for the reasons disclosed in Paper No. 10, Sections 5© p. 10, and 5(d) p. 11, Paper No. 15 Section 8, page 7 and Paper No. 27, Section 8, pages 7-8.

Because Applicant did not distinctly and specifically point out the supposed errors in the rejection, the rejection is maintained.

8. Claims 71-72 and 77-79 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 27, Sections 12-13, page 10.

Although Applicant submitted an amendment to the claims in response to the instant rejections, the amendment has not been entered for the reasons set forth above. The rejections are maintained for the reasons of record.

9. Claims 69-83 remain rejected under 35 USC 112 second paragraph for the reasons previously set forth in Paper No. 27, Section 14, page 10.

Although Applicant submitted an amendment to the claims in response to the instant rejections, the amendment has not been entered for the reasons set forth above. The rejections are maintained for the reasons of record.

Art Unit: 1642

Claim Rejections - 35 USC § 102

10. Claims 69-83 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 10, Section 8 pages 16-18, Paper No. 15, Section 10, pages 8-9 and in Paper No. 27, Section 11, page 9.

Applicant argues that according to the Merck index all of the drugs listed on Page 9 of WO 91/19134 are soluble and it would be expected that the recited pro-drugs, when converted into active drugs were soluble because such non-radioactive drugs must be soluble in order to diffuse through cancer and as drawn to radioactive drugs, there is no way to make a therapeutically radioactive pro-drug inherently less toxic than the active drug. The arguments have been considered but have not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted. The claims are not drawn to a prodrug but to a therapeutic agent. Further, Applicant has not presented objective data that any of these soluble therapeutics can not undergo precipitation. Applicant states that they do not undergo soluble to insoluble conversion as does the first therapeutic agent of the present invention, however, the claim as written only requires that the agent be a precipitable material. Since the claim is not drawn to a method, disclosure of intended use in the claim is not limiting.

11. All other objections and rejections recited in Paper No. 27 are withdrawn.

12. No claims allowed.

13. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

Art Unit: 1642

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

Serial No: 08/782,590

Page 8

Art Unit: 1642


Susan Ungar

Primary Examiner

February 12, 2001

